July 29, 2020

Walk Vascular, LLC
Brad Culbert
VP of Engineering
17171 Daimler Street
Irvine, California 92614

Re: K140296
Trade/Device Name: ClearLumen Thrombectomy System
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy catheter
Regulatory Class: Class II
Product Code: QEZ

Dear Brad Culbert:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated December 2, 2014. Specifically, FDA is updating this SE Letter because FDA has created a new product code to better categorize your device technology.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Gregory O'Connell, OHT2: Office of Cardiovascular Devices, (301) 796-6075, Gregory.Oconnell@FDA.HHS.gov.

Sincerely,

Gregory W. O'connell -S

Digitally signed by Gregory W. O'connell -S
Date: 2020.07.29 19:02:55 -04'00'

Gregory O'Connell
Assistant Director
Plaque Modification Devices Team
DHT2C: Division of Coronary
and Peripheral Intervention Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

December 2, 2014

Walk Vascular, LLC
Mr. Brad Culbert
VP Engineering
17171 Daimler Street
Irvine, California 92614

Re: K140296
Trade/Device Name: ClearLumen Thrombectomy System
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: DXE
Dated: November 21, 2014
Received: November 24, 2014

Dear Mr. Culbert,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Precautions section of the device's labeling:

> The safety and effectiveness of this device for use in the treatment of ST-Elevation Myocardial Infarction (STEMI) have not been established. Complications from the use of this device in this manner could lead to death, permanent impairment, and/or the need for emergency medical intervention.

Furthermore, the indication to remove/aspirate fluid and break-up soft emboli and thrombus from the coronary and peripheral vasculature must be prominently displayed in all labeling, including pouch box, and carton labels, instructions for use, and other promotional materials, in close proximity to the trade name, of a similar point size, and in bold print.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

William H. Maisel -S

William H. Maisel, M.D., M.P.H.
Director
Office of Device Evaluation (Acting)
Deputy Center Director for Science
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number if Known: K140296

Device Name: ClearLumen Thrombectomy Device

Indications for Use:

The ClearLumen Thrombectomy System is intended to remove/aspirate fluid and break-up soft emboli and thrombus from the coronary and peripheral vasculature.

Prescription Use ☒ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrent of CDRH, Office of Device Evaluation (ODE)

K140296
Traditional 510(k) Summary

Submitter: Walk Vascular, LLC
17171 Daimler Street
Irvine, CA 92614

Contact: Brad Culbert
VP Engineering
Walk Vascular LLC
Telephone: 949.752.9642
Fax: 949-752-9658
Email: bsculbert@yahoo.com

Date Summary Prepared: 25 November 2014

Device Trade Name: ClearLumen Thrombectomy System

Common Name: Embolectomy / Thrombectomy Catheter

Classification Name: Embolectomy Catheter (21 CFR §870.5150)

Product Code: DXE

Predicate Devices: Walk Vascular ClearLumen Thrombectomy System (K120508)
Medtronic Export AP Aspiration Catheter (K081573)

Device Description:
The ClearLumen Thrombectomy System consists of a thrombectomy catheter, saline drive unit ("SDU") and aspirate collection vacuum bottles. The 6 Fr, 135 cm, multi-lumen thrombectomy catheter delivers pressurized saline, within the distal catheter I.D., to assist in the break-up and removal of soft emboli and thrombus. The distal catheter's .014" wire compatible rapid exchange lumen extends and ends in a soft atraumatic tip. The catheter's proximal polycarbonate hub connects to the SDU and provides coaxial access to the infusion and aspiration lumens. The ClearLumen Catheter is connected to the battery operated SDU, which includes a pump to generate pressurized saline and conduit/collection of aspirate. The SDU uses a toggle switch to turn the pump on and off and actuate a valve in line to a pre-charged vacuum bottle (aspiration source). The SDU connects via spike to a standard saline bag (saline source).

Intended Use:
The ClearLumen Thrombectomy System is intended to remove/aspirate fluid and break-up soft emboli and thrombus from the coronary and peripheral vasculature.

Statement of Equivalence:
The subject and the predicate ClearLumen Thrombectomy Systems share the same technological characteristics (design, energy source, materials, sterilization and aspiration catheter with saline stream). The technological differences between the two ClearLumen systems include dimensional changes (OD and length to be compatible with coronary .014" wires and 6F guide catheters) and design changes of the distal section of the catheter to improve flexibility and trackability for coronary use. The subject device and the predicate Medtronic Export AP device share the same intended use and compatibility with procedural accessories (i.e. 0.014" guidewire and 6F Guiding Catheter use). Differences between the subject device and the predicate Export AP device include the predicate's indication for use inclusion to sub selectively

infuse/deliver diagnostics or therapeutic agents with or without vessel occlusion, the predicate device use of syringes for aspiration (compared to the subject device's pre-charged vacuum bottles for aspiration), and the subject device utilizes a saline stream within the aspiration lumen to assist in thrombus removal.

The ClearLumen Thrombectomy System is substantially equivalent to the predicate devices, with regards to its intended use, design, function, materials and sterilization method.

Summary of Non-Clinical Performance Data:

Device evaluation consisted of *in-vitro* testing performed pursuant to Walk Vascular's risk analysis. All data met the acceptance criteria and fell within pre-determined product specifications and external standard requirements. The following testing was performed:

Design Verification Testing:

Pull test of welded and glued joints
Dimensional analysis
Vacuum pump circuit and vacuum integrity
Vacuum bottle attachment and fill verification
Vacuum leakage
Leak testing
Pressure testing
Flow testing
Kink testing
Push / track performance
Particulate testing
Embolic analysis
Saline stream containment
60601-1 Product and electrical safety testing
Lubricity & durability
Battery life testing

Biocompatibility Testing (GLP)

Biocompatibility testing was conducted according to ISO 10993 "Biological Evaluation of Medical Devices – Part 1 – Evaluation and testing requirements".

Sterilization Testing

Sterilization validation was conducted according to ISO 11135 "Ethylene Oxide Sterilization, Validation and Routine Control" to ensure a sterility assurance level (SAL) of 10^{-6}.

Transportation and Shelf Life Testing

Shipping and Distribution testing was conducted in accordance to ISTA 2A "Performance test for individual packaged products 150lbs or less."

Shelf life testing was performed.

The data from the *in-vitro* testing above support the substantial equivalence of the subject to the predicate devices.

Summary of Pre-Clinical and Clinical Data:

Pre-clinical and clinical device evaluation was performed in an *in-vivo* GLP animal study and an OUS human clinical trial. The data from the porcine in-vivo study was able to demonstrate an acceptable safety and performance profile of the ClearLumen device.

The human clinical study, Thrombus Aspiration with the ClearLumen Catheter During Primary Percutaneous Coronary Intervention Clinical Trial, was a prospective, single center, non-randomized, 20 subject study. In this study, the ClearLumen Thrombus Aspiration System was used as an adjunctive therapy in primary Percutaneous coronary intervention in patients with ST-segment elevation (STEMI). The average age of the treated subjects was 68.6 years. The majority of the treated subjects were male (60%). Fifteen percent of the population have diabetes; 40% have hypertension requiring medical therapy; and, 40% have a history of smoking. Ten percent of the subjects reported a prior history of coronary disease. Other previous conditions reported included lung cancer (1) and Chronic Obstructive Pulmonary Disease (COPD) (1). Safety and efficacy was evaluated during the procedure, through 30-day follow-up and study success defined by the study two primary end points of Myocardial Blush Grade (MBG) ≥ 2 and final Thrombolysis In Myocardial Infarction (TIMI) flow grade = 3. No Major Adverse Coronary Events (MACE) or device related Significant Adverse Events (SAE) were reported in this study.

Summary:

Based on the intended uses, *in-vitro* performance and biocompatibility information provided in this pre-market notification, the ClearLumen Thrombectomy System is as safe and effective as the predicate devices.